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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/828,539 | 04/04/2001 | Howard Preissman | 361722000201 | 9912 |

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| EXAMINER |
|---|
| MILLER, CHERYL L |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3738 | |

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/828,539 | PREISSMAN, HOWARD | |
| | Examiner | Art Unit | |
| | Cheryl L. Miller | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *33-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Specification*

1. The abstract of the disclosure is objected to because of minor informalities. Spelling and wording of "bout" in line 7 are suggested to be changed to "between about." Correction is required. See MPEP § 608.01(b).

### *Double Patenting*

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 33, 34, 35, 36 and 38-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9, 10, 14, 11 and 12-13 respectively, of U.S. Patent No. 6,309,420. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 33 of applicant discloses that a composition is injectable and biocompatible. It is obvious in the art, to use biocompatible materials for implantation for the purpose of reducing the chance of material rejection. It is also common in the art to use injection as a method of implantation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the composition of claim 9, patent 6,309,420 by choosing a biocompatible material, which could be implanted into the body by means of injection. Referring to claims 34-35 of applicant, formation of a

slurry and a hard tissue implant material are disclosed by Patent 6,309,420 in claims 10 and 14 respectively. Radiopaque particle sizes disclosed in claims 36, 38, and 39 are equivalent to sizes disclosed in claims 11, 12, and 13 respectively of Patent 6,309,420.

4. Claim 37 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,309,420. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1 and 2 of Patent 6,309,420 disclose use of radiopaque particles, whereas claim 37 of applicant discloses use of contrast particles. It is common knowledge in the prior art that radiopaque and contrast particles are similar in that they both provide radiographic contrast for viewing during implantation or removal.

5. Claims 40-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1 and 9 of U.S. Patent No. 6,309,420. Although the conflicting claims are not identical, they are not patentably distinct from each other. The applicant simply discloses in claim 40, use of medical fluoroscopy in order to monitor particle presence. Claim 1 of 6,309,420 discloses the same enhanced visibility composition. Claim 1 discloses particles ability to be discretely viewable during implantation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use medical fluoroscopy, whose purpose is to view particles during implantation of composition. Radiopaque particle sizes disclosed in claim 41 of applicant are equivalent to sizes disclosed in claims 1 and 9 of U.S. Patent 6,309,420.

### *Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 33 and 35-39 rejected under 35 U.S.C. 102(b) as being anticipated by Ersek et al. (U.S. Patent 5,258,028). Ersek et al. discloses an injectable composition that includes all limitations set forth in the claims. See figures 3-6 and respective portions of specification. Referring to claim 33, figures 3 and 4 of Ersek et al. show an injection of a composition into a patient (col.2, lines44-45;col.4, lines21-34). Ersek et al. discloses a composition comprising a biocompatible matrix (col.2, lines47-67;col.8, line18) and radiopaque particles (col.3, lines55-60; col.10, lines23-28, figure 5 and 6).

Ersek et al. discloses a particle size comparable to sizes of larger radiopaque particles and of smaller contrast particles (barium compounds, col.10, line24;col.6, lines8-33) specified in claims 33 and 36-39 (col.2, lines35-39;col.6, lines34-41).

Referring to claim 35, Ersek et al. discloses a composition for hard tissue applications (col.3, lines52-60;col.9, lines48-63).

8. Claim 40 is rejected under 35 U.S.C. 102(e) as being anticipated by Wallace et al. (U.S. Patent 6,103,254). Wallace et al. discloses and enhanced visibility composition that includes all limitations set forth in the claim. Wallace discloses a composition of a flowable matrix (col.5, lines42-47) and

radiopaque particles (col.1, lines10-13;col.5, lines62-63), which are visible under fluoroscopy (col.5, lines62-65;col.10, lines31-34)

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. in view of Lawin et al. (U.S. Patent 5,451,406). Ersek et al. discloses the invention substantially as claimed. Ersek et al. discloses an injectable composition made of a matrix and radiopaque particles, however does not disclose said composition to form a slurry. Lawin et al. teaches in the same field of endeavor and discloses an injectable composition, which forms a slurry (col.4, lines41-42) in order to ease injection. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose a matrix material such as Lawin et al. in order to form a slurry for injection ease.

11. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al in view of Ersek et al. Wallace et al. discloses the invention substantially as claimed. Wallace et al. discloses a composition including a radiopaque material or contrast agents to enhance visibility during fluoroscopy, however discloses radiopaque particles of a smaller size than the size claimed (col.10, line32-33;col.3, lines8-10;col.7, line1). Ersek et al. teaches in the same field of endeavor, a composition wherein said radiopaque particles are larger in size, similar to as claimed (col.2, lines35-39;col.6, lines8-41) for the purpose of limiting migration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to enlarge said radiopaque particles in order to decrease migration and increase visibility even more so during fluoroscopy.

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 5,476,880 to Cooke et al. discloses a method of preparing a flowable composition made up of a PMMA matrix and radiopaque particles to replace hard bone.

U.S. Patent 5,114,240 to Kindt-Larsen et al. discloses a method for preparing a composition made of a flowable matrix and contrast agents to be injected into hard bone, while being viewed by a radiograph.

U.S. Patent 6,077,916 to Laurencin et al. discloses a mixture a biocompatible polymer matrix and imaging agents for view under fluoroscopy during bone repair.

U.S. Patent 5,837,752 to Shastri et al. discloses a composition made up of a polymer matrix and contrast agents for tracing by fluoroscopy during bone repair.

U.S. Patent 5,919,434 to Dugstad et al. discloses use of gas containing contrast agents for improved visibility during imaging.

U.S. Patent 6,080,801 to Draenert et al. discloses a process for preparing polymer beads with radiographic contrast agents contained within said bead.

U.S. Patent 4,500,658 to Fox discloses a process for preparing radiopaque resin beads.

U.S. Patent 5,717,006 to Daculsi et al. discloses an injectable composition for bone by use of hydroxyapatite.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday-Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

David H. Willse
Primary Examiner

Clm
12/17/01